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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,468	12/06/2004	Tatsuaki Suzuki	KUZ-0021	1362
7590 Licata & Tyrrell 66 East Main Street Marlton, NJ 08053				
			EXAMINER PALENIK, JEFFREY T	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/11/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,468

Applicant(s)

SUZUKI ET AL.

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' amendments and remarks filed 4 February 2009 are acknowledged and entered on the record. The Examiner acknowledges the following:

Claims 1 and 2 have been cancelled, the limitations of which are combined into new independent claim 13.

Claims 14 has also been added. Support for the claim is found in Applicants' originally submitted claim 2.

Newly submitted claim 15 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: had the method of preparation as recited in claim 15, been presented as a part of the original claims, said invention would have precipitated an Office Action requiring a restriction between the claimed inventions.

Since Applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 15 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 3-11 have been amended to depend from newly added independent claim 13.

Thus, claims 13, 3-12, 14 and 15 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendment to the Abstract of the Invention has been considered fully and is persuasive. Thus, said objection has been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendments changing " μmR_s " (cancelled claims 1 and 2) to " μm " to reflect the surface roughness recitation in new claim 13, render moot their rejections, under 35 USC 112, first paragraph. Thus, said rejection has been **withdrawn**.

Rejection under Nonstatutory Double Patenting

Applicants' discussion of the surface roughness property with respect to the polyester-based film taught by the combined references of Chono et al. (USPN 6,139,866) and Wick et al. (USPN 6,129,929) has been fully considered and is **persuasive**. Since the combination of the two references does not teach the property or the motivation for achieving it, the rejection of claims 1, 6-9, 11 and 12 on the grounds of nonstatutory obviousness-type double patenting over Chono et al. in view of Wick et al. is rendered moot. Thus, said rejection has been **withdrawn**.

Rejection under 35 USC 103(a)

Applicants' remarks, as discussed above, render moot the rejection to claims 1-12, under 35 USC 103(a), as being unpatentable over the combined references of Chono et al. and Wick et al. Per the aforementioned interview and resulting submitted remarks, the surface roughness is a

structural limitation of the polyester-based film not addressed by either of the references. Thus, said rejection now stands **withdrawn**.

Rejection under 35 USC 102(b)

Applicants' remarks, as discussed above, render moot the rejection to claims 1-8 and 10-12, under 35 USC 102(b), as being anticipated by Chono et al. Per the aforementioned interview and resulting submitted remarks, the surface roughness is a structural limitation of the polyester-based film not addressed by either of the references. Thus, said rejection now stands **withdrawn**.

NEW REJECTIONS

In light of Applicants' remarks and amendments, most notably the cancellation and combination of claims 1 and 2 to form new claim 13, as well as Applicants' remarks regarding the surface roughness of the polyester-based film, the following rejections have been newly added:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 5, 9, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. (USPN 6,139,866) and Tomaru et al. (USPN 6,563,195).

Newly added independent claim 13 is drawn to a patch comprising a polyester-based film and a drug-containing adhesive layer, wherein the adhesive-contact side of the polyester film has a surface roughness ranging from 0.05-0.8 microns and wherein the film contains no pinholes. Claim 5 recites that the polyester-based film is polyethylene terephthalate (PET). Claim 9 recites that the area of the composition of claim 13 ranges from 5-60 cm². With regard to the limitation recited in claim 10, which states "the bending stiffness of a substrate is from 10-80 mm"; until some material difference in the properties of the composition is demonstrated, said limitation is considered by the Examiner to be directed toward the polyester-based substrate, which is instantly claimed. Claim 14 recites that the polyester-based film "is sandblasted" prior to being contacted with the drug-loaded adhesive layer. Said limitation is interpreted by the Examiner as a product-

by-process limitation (MPEP §2113) which states that even though the claim is limited by and defined by the process, determination of patentability is based on the product itself.

Chono et al. expressly teach a percutaneous tape formulation comprising a drug which is immersed within an adhesive layer (claim 1), which may then be applied to a 30-micron PET film (Example 2). The teachings of Chono are further silent to the presence of “pinholes” in the PET film layer, which is interpreted by the Examiner as the film layer being free of said pinholes.

Chono neither expressly teaches the instantly claimed PET film as having a surface roughness ranging from 0.05-0.8 microns on the side which contacts the adhesive layer nor the instantly claimed area limitation.

Tomaru et al. teach preparing a base sheet by “blasting” it in order to achieve a textured surface, to which is adhered a silicone rubber layer having substantially uniform thickness (col. 2, lines 17-24). The base sheet is taught as being a film of uniform thickness, advantageously prepared from polyethylene terephthalate (PET) and having a thickness ranging from 25 to 1,000 microns (col. 3, lines 49-57). It is further taught that if the film is too thin then it lacks the desired stiffness, whereas if it is too thick, then it becomes difficult to work with (col. 3, lines 54-59). Lastly, the surface roughness imposed on the film is taught as ranging preferably from 0.3-2.0 microns. Example 1, in particular, expressly teaches blasting a PET film in order to achieve a surface roughness (R_a) of 0.8 microns after which the silicone rubber layer is directly applied.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have polished or “blasted” the polyester-based film of Chono to the

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desired surface roughness prior to the application of an additional layer, particularly one with adherent properties because to do so advantageously increases the interlayer friction. The ordinarily skilled artisan would have been particularly motivated to do so because polishing a PET film as taught by Tomaru not only inherently teaches that the surface area to which the adherent layer is applied is increased, but more critically, it teaches that the layer which is applied after blasting is more securely adhered to the film, thereby reducing overall slippage between the two layers (col. 1, lines 45-52 and col. 3, lines 29-40).

Furthermore, regarding Applicants' instantly claimed area range, it is noted by the Examiner that the value or format of a parameter (e.g. area of a patch) with respect to the claimed composition is adjustable. It thus follows that adjusting the size of such a patch formulation is a result-effective parameter that a person having ordinary skill in the art would be motivated to easily and routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. For example, Example 1 of Tomaru teaches that the blasted and layered PET base film is 400 mm or 40 cm wide. Though, the length of the film is not expressly discussed, it would have been customary for an artisan of ordinary skill, to adjust the length of said film in order to achieve a patch having an area such as that which is instantly claimed. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

Based on the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

Claims 3, 4, 6-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. with respect to new independent claim 13, as set forth above.

Claim 13 is drawn to a patch comprising a textured, polyester-based film and a drug-containing adhesive layer, as discussed above.

Claim 3 recites that the thickness of the polyester-based substrate ranges from 5-40 microns, whereas claim 4 recites an adhesive layer thickness ranging from 50-125 microns. These limitations are expressly taught by Example 2 which teaches the application of a 100-micron adhesive layer mixture to a 30-micron PET film.

Claims 6 recites that the adhesive layer comprises the block copolymer styrene-isoprene-styrene (SIS). Claim 7 recites that the adhesive layer comprises both SIS copolymer as well as polyisobutylene (PIB). Claim 8 recites that the adhesive layer further comprises a tackifier, a plasticizer, or both. Claims 11 and 12 recite that the drug contained by the adhesive layer is a narcotic analgesic such as fentanyl or a fentanyl salt. These limitations are also expressly taught by Example 2, wherein the mixture applied to the PET film comprises both SIS block copolymer and polyisobutylene, polyterpene resin tackifier, as well as fentanyl citrate.

All claims have been rejected; no claims are allowed.

CONCLUSION

Due to the new grounds of rejection, this action is deemed **non-final**.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615